REMARKS

This paper is responsive to the Office Action mailed June 13, 2006. Claims 1-31 are pending in the application. Claims 12-21, 30 and 31 have been allowed. Claims 10 and 11 were objected to, and claims 1-9 and 22-28 stand rejected.

Rejections and objections related to claims 5 and 29

Claims 5 and 29 were rejected under 35 USC §112 as being indefinite. Specifically, the Examiner stated that the claim terms "receptacle" and "cap" were considered vague. In addition, claims 5 and 29 were objected to on the basis that it was unclear what structure related to the "receptacle" and the "cap". Furthermore, the drawings were objected to due to the alleged failure to show the receptacle and cap in the figures. These rejections and objections will be dealt with together.

Applicants respectfully assert that the elements "receptacle" and "cap" are properly identified and explained in the specification, are not vague or indefinite as used in the specification and/or the claims, and are clearly and properly shown in the drawings. The "receptacle" referred to in claim 5 is shown as reference numeral 39 in Fig. 3. The receptacle is also discussed at paragraph [0031] of the specification. For the Examiner's convenience, a portion of this paragraph is reprinted below, with the relevant text highlighted:

> [0031] Fig. 4 is a perspective view of one embodiment of a flange 32 that is selectively attachable to, and removable from, tracheostomy tube 20. Tracheostomy tube flanges are well-known, and flange 32 may have any general shape commonly utilized for this purpose. ..... **Snaps 38 are snap-fit into complementary receptacles 39 in tracheostomy tube body 21 (only one of which is shown in the view of Fig. 3) to securely, but removably, affix flange 32 to tracheostomy tube 20.** Once attached to the tracheostomy tube, the flange functions in the same manner as a non-removable flange on a conventional tracheostomy tube.

Similarly, the "cap" is shown as reference numeral 74 in Figs. 7-9. The "cap" referenced in claim 29 is described at various portions of the specification, such as in paragraphs [0042] and [0044]. For the Examiner's convenience, a portion of paragraph [0042] is reprinted below, with the relevant text highlighted:

> [0042] Therefore, a lock mechanism is provided to prevent such excess penetration of the tracheostomy tube. In the embodiment shown in Fig. 7, the lock mechanism comprises a stop mechanism 72 that is provided on dilator 70. **A securement member 74 is provided for engagement with the stop mechanism. In this embodiment shown, the stop mechanism is an annular ring and the securement member is a rotatable cap.** ....

As is clear from the explanation herein, the "receptacle" and the "cap" are clearly identified in both the specification and the drawings.

Rejections under 35 USC 102(b)

(a) Claims 1, 2, 8 and 9.

In the Office Action, Claims 1, 2, 8 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Fauza (USP 6,612,305). Fauza discloses a tracheostomy tube 2 having a balloon 1 with a self-described "integral" design. The balloon is said to differ from conventional balloons in that it not only expands around the tube 2, but also cranially to it and to the stoma. A movable neck flange 3 is provided. According to the patent, the movability of the flange adds safety by allowing strap fixation around the patient's neck at different distances from the balloon. Col. 4, lines 6-8.

Claim 1 has been amended herein to incorporate limitations from original claim 2. Claim 2 has now been canceled. Claim 1, as amended, is directed to a tracheostomy tube that comprises a hollow tubular body having a curved portion intermediate respective proximal and distal end portions. A flange situated at said proximal end portion is capable of selective attachment to the proximal end portion and detachment therefrom. The flange extends radially from the proximal end portion when attached thereto. Thus, unlike the flange described in Fauza, the flange of claim 1, as amended, is capable of selective attachment to and detachment from the proximal end of the hollow tubular body during a tracheostomy procedure.

The inventive tracheostomy tube finds particular utility when used in combination with a radially expandable introducer sheath, such as the prior art sheath shown in Fig. 1 of the present application. When a radially expandable sheath of this type is utilized for the introduction of a tracheostomy tube that has a conventional flange projecting therefrom in the radial direction, it becomes difficult to withdraw the sheath following insertion of the tracheostomy tube therethrough. In this instance, the

flange portion of the tube is situated directly in the path of the withdrawing sheath, thereby obstructing the withdrawal of the sheath. By utilizing a flange that may be selectively attached to and detached from the proximal end of the tracheostomy tube during a tracheostomy procedure, the tube can be introduced into the trachea via the radially expandable sheath. Following placement of the tracheostomy tube, the flange can be detached from the tracheostomy tube, and the introducer sheath can simply be withdrawn in the proximal direction over the tube. Since the flange has been removed from the tube, there is no radially extending structure present on the tube body that obstructs the withdrawal.

The tracheostomy tube/flange combinations in Fauza do not teach or suggest this feature. Rather, Fauza teaches a "movable" neck flange. Contrary to the assertions of the Examiner in the Office Action, there is nothing in Fauza that suggests that this flange is capable of selective attachment to and detachment from the proximal end of the tube, as claimed in amended claim 1. Rather, it appears to be simply movable or pivotable in some manner at the site of its attachment to the tube to facilitate attachment of a strap. In the Office Action the Examiner cited a portion of Fauza ("A movable flange (3) allows for extra fixation of the device around a patient's neck, see abstract, see also, col.4 lines 9-10)" as support for teaching a removable flange. However, Applicants respectfully submit that the cited portion of Fauza is referring to movement, or adjustment, of the flange in a manner such that a strap can be fixed around a patient's neck at different distances from the balloon, depending on the local anatomy of the patient. Fauza neither teaches nor suggests the selective attachment of the flange to, and/or detachment from, the proximal end portion of the tube. At most, Fauza teaches a flange that may be maneuvered in some manner to permit fixation of a strap around the neck of a patient. The Examiner seems to have equated a "movable" flange, with a detachable flange. Applicants respectfully submit that there is nothing in Fauza to suggest such an extension of the actual teaching of Fauza.

Based on the foregoing, Applicants respectfully submit that independent claim 1, as well as dependent claims 8 and 9, are not anticipated by Fauza.

(b) Claim 22.

Claim 22 was rejected under 35 USC 102(b) as being anticipated by Hazard (USP 5,058,580). The Hazard patent is directed to a tracheostomy tube comprising a tubular cannula having a tapered distal end portion that forms a smooth transition insertion area. The distal end portion is beveled at one side to facilitate percutaneous insertion of the tracheostomy tube into a patient's trachea through a stoma in the neck between adjacent cartilages. The proximal end portion of the tube includes an integrally molded flexible neck flange 26. Flange 26 is used in conjunction with apertures 27 and a suitable strap to secure the tracheostomy tube 10 in position at the neck of the patient. The proximal end portion 16 of the device includes a standard coupler 28 for connecting the tracheostomy tube to a respirator system. Col. 4, lines 43-50.

Claim 22 is directed to a device for percutaneous insertion into the trachea of a patient. The device comprises a tracheostomy tube having a longitudinal passageway therethrough. The distal end portion of the tracheostomy tube is percutaneously insertable into the trachea, and a proximal end portion is exterior to the trachea when the distal end portion is inserted. The tracheostomy tube further has a radially extending flange attachable to the proximal end portion of the tracheostomy tube *after the distal end portion has been inserted into the trachea*. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea. A locking assembly is provided for locking the tracheostomy tube to the dilator during insertion of said tracheostomy tube into the trachea.

First, Applicants submit that Hazard does not teach or suggest an arrangement wherein the tracheostomy tube has a radially extending flange attachable to the proximal end portion of the tracheostomy tube after the distal end portion has been inserted into the trachea. Rather, as stated, the flange in Hazard is integral with the tracheostomy tube. It is not added, and cannot be added, after the distal end portion has been inserted into the trachea.

Secondly, the Examiner stated that the Hazard device includes a locking assembly for locking the tracheostomy tube to the dilator during insertion of the tube into the trachea. In support thereof, he cited reference object 37 in Fig. 1 [5?], and Col. 5, lines 20-25 of the specification (referred to therein as a "flange".). Upon

review of the pertinent portions of the Hazard patent, Applicants respectfully dispute the Examiner's characterization of reference object 37 as a "locking assembly", and the depictions in the patent specification as referring to such an assembly. Reference object 37 merely refers to a flange portion that limits the depth to which the obturator can be inserted. There is no apparent locking action. In the present application, on the other hand, an actual locking assembly is provided. The locking assembly is discussed, among others, at paragraphs [0041] to [0044], and illustrated at Figs. 7-9. In the preferred embodiment shown, the locking mechanism comprises a stop mechanism 72, and a securement member 74 that engages with the stop mechanism. As illustrated, the stop mechanism is preferably an annular ring, and the stop mechanism is preferably a rotatable cap. In the embodiment shown, the cap includes screw threads or other attachment mechanism for locking the securement member to a complementary attachment site on the tracheostomy tube, such as collar 22. Thus, as a result of this interconnecting structure, there is actual "locking" action that takes place in the inventive device. No such action is observed in the cited portions of the Hazard disclosure, nor does there appear to be any structure capable of providing locking action. Applicants repeat their request first presented in an earlier Response that the Examiner clarify the basis upon which object (flange) 37 can be considered to be a locking mechanism that is capable of locking the tracheostomy tube to the dilator during insertion of the tracheostomy tube into the trachea.

Based on the foregoing, Applicants respectfully submit that independent claim 22 is not anticipated by Hazard.

Rejections under 35 USC §103(a).

(a) Claim 3.

Claim 3 was rejected under 35 USC §103(a) as being unpatentable over Fauza. As amended, claim 3 is now dependent on claim 1, and includes the additional limitation that the flange is attachable to the tube by a snap-fit. In the Office Action, the Examiner stated that "Fauza's disclosure of a flange with a strap attachment is considered an equivalent structure capable of securing the flange to the tube." However, as stated previously, Fauza does not teach a flange that is attachable to a tube. The strap described in Fauza is provided to strap the

tracheostomy tube to the patient's neck. It does *not* secure the flange to the tube in the manner of the snap-fit of the present claim. Thus, Applicant's submit that claim 3 is not unpatentable in view of Fauza.

(b) Claims 4, 6, 7, 23-28.

Claims 4, 6 and 7 were rejected under 35 USC §103(a) as being unpatentable over Fauza in view of Roy (USP 6,135,110).

Claim 4 is dependent on claim 3, and includes the further limitations that the hollow tubular body includes a collar at its proximal end, said collar having a groove, and wherein the flange includes a cut-away portion, wherein the cut-away portion and said groove are cooperatively sized and shaped to mate when the flange is attached to the tube. Since claim 4 is dependent on claim 3, it includes all the limitations of claim 3 including the limitation regarding a flange attachable to the tube by a snap-fit. The cited references, either individually or in combination, fail to teach or suggest this arrangement.

Claim 6 is dependent on claim 4, and includes the further limitation that the collar is integral with the hollow tubular body. Claim 7 is also dependent on claim 4, and includes the further limitation that the collar includes one or more barbs for attaching the collar to the hollow tubular body. Since these claims are dependent on claim 4, they include all the limitations of claims 3 and 4 set forth above. The cited references, either individually or in combination, fail to teach or suggest this arrangement. It is further noted that the snap-fit of Roy does not relate to snapping a flange to a tracheostomy tube. Rather, Roy teaches a pressure adjusting mechanism for fixedly mating an inner cannula to an outer cannula. Further, it is noted that the collar of Roy is coupled to the inner cannula, unlike the arrangement of the present invention wherein the collar is engaged with the tracheostomy tube.

(c) Claims 23-28.

Claims 23-28 were rejected under 35 USC §103(a) as being unpatentable over Fauza in view of Roy (USP 6,135,110).

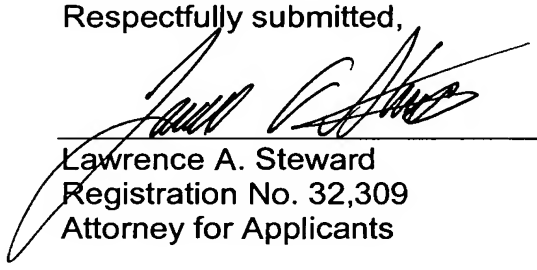
Claims 23-28 are dependent, directly or indirectly, on claim 22 and include all of its limitations, including the limitation of a radially extending flange attachable to the proximal end portion of the tracheostomy tube after the distal end portion has been

inserted into the trachea, and a locking assembly for locking the tracheostomy tube to the dilator during insertion of the tracheostomy tube. Applicants have previously set forth that Hazard fails to teach or suggest a flange or a locking assembly as claimed. It is further noted that Roy also fails to set forth a flange or a locking assembly as claimed. Therefore, Applicants respectfully submit that the cited references, either individually or in combination, fail to teach or suggest the features of the present claims. Accordingly, Applicants submit that claims 23-28 are allowable for at least the same reasons that claim 22 is allowable.

Conclusion.

For the reasons provided hereinabove, Applicants respectfully submit that all claims 1 and 3-31 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution may be advanced by a telephone conversation, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,



Lawrence A. Steward
Registration No. 32,309
Attorney for Applicants

LAS/cbw

BRINKS HOFER GILSON & LIONE
CUSTOMER NO. 48004
(317) 636-0886